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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,456	07/19/2001	Murdo M. Black	5017-8121	9669
21888	7590	10/08/2003	EXAMINER	
THOMPSON COBURN, LLP ONE US BANK PLAZA SUITE 3500 ST LOUIS, MO 63101			QUAN, ELIZABETH S	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,456

Applicant(s)

BLACK, MURDO M.

Examiner

Elizabeth Quan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the adhered tape or pad, embossed structure, mesh layer, and total thickness of the non-working area greater than or equal to the total thickness of the working area must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 is rendered indefinite since it is unclear whether the *fluid to be applied* or the test member contains the reagent.

5. Claim 12 provides for the use of the test member, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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Claim 12 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 5, 6, 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/13101 to Hughes et al.

Hughes et al. disclose a test member suitable for use in a test device for testing of analyte concentration in a fluid applied thereto, such as blood glucose (ABSTRACT; FIG. 1; PAGE 5, lines 20-32; PAGE 7, lines 22-24). The test member comprises a base member (1) with a working area exposed by aperture (14) of cover layer (13) and v-shaped channel flow channel (30) of dielectric coating (11) to which an aqueous sample is applied (FIG. 1; PAGE 9, lines 21-29). Since the sample is aqueous, the sample contains a reagent, such as water. Furthermore, the test member contains a reagent, such as an enzyme, mediator, and filler provided by inks forming working electrode working area (8) and dummy electrode working area (8a) reactive to the analyte to produce an electrical signal or color change in response to the concentration of analyte in the aqueous sample (ABSTRACT; PAGE 6, lines 20-25; PAGE 7, lines 8-33; PAGE 11, lines

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3-13). A non-working area is adjacent to the working area (FIG. 1). Since the working area is defined as the area exposed by aperture (14) of the cover layer (13) and v-shaped channel flow channel (30) of dielectric coating (11) in which solid portions of both cover layer (13) and dielectric coating (11) extend into the non-working area such that the thickness of the cover layer (13) and dielectric coating (11) is not part of the working area, the total thickness of the test member in at least a portion of the non-working area is greater than the total thickness of the test member in the working area by at least the combined thickness of the cover layer (13) and dielectric coating (11) (FIG. 1). The cover layer (13) is preferably made of a flexible polyester tape (PAGE 9, lines 12 and 13). The non-working area supports three printed tracks of electrically conducting carbon ink (2) (PAGE 6, line 34-PAGE 7, line 1). The mesh layer (10), which is primarily located in the working area, continuously extends into a small portion of the non-working area (FIGS 1 and 5B). The test member has a plurality of electrode tracks (3) exposed on a portion of the non-working area for connection to corresponding electrodes of a meter of a test device to transmit electrical signals (PAGE 11, lines 3-13).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 3, 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/13101 to Hughes et al.

Hughes et al. do not quantify the total thickness the non-working area is greater than the working area by. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimal total thickness of 1 to 20 micrometers or more specifically 5 to 10 micrometers that the non-working area is greater than the working area by since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 233) and since it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device (*Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984)).

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/13101 to Hughes et al. in view of U.S. Patent No. 5,885,429 to Friese et al.

Hughes et al. do not explicitly disclose an embossed structure. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have embossed the electrodes, which are on at least part of the non-working area, as taught by Friese

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et al. to form contouring for an enlargement of the effective electrode surface and accomplishing greater mechanical stability of the electrode or the test member provided with the electrode, such that handling of the test member during the production process is improved (COL. 2, lines 11-37).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. They include one or more limitations in the claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan
Examiner
Art Unit 1743

eq


Jill Warden
Supervisory Patent Examiner
Technology Center 1700